

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----- X
GOJO INDUSTRIES, INC.,

Plaintiff,

- against -

INNOVATIVE BIODEFENSE, INC.; and AQUARIUS
GLOBAL ENERGY PARTNERS, LLC,

Defendants.
----- X

:
: 15 Civ. 2946 (PAC)
:

: **COMPLIANCE REPORT**
:

Dan Putalik declares as follows under penalty of perjury that the foregoing is true and correct:

1. I am a Managing Director of Aquarius Global Energy Partners, LLC (“Aquarius”), and I submit this report pursuant to the April 24, 2015 Stipulation and Order (the “Order”) in this action. The Order required Aquarius to submit a report to the Court “setting forth the manner and form in which Aquarius complied with its obligation to issue corrective notice pursuant to this Order.”

2. On May 1, 2015, counsel for Aquarius and counsel for plaintiff GOJO Industries agreed upon a form of corrective notice (the “Corrective Notice”), a copy of which I attach as Exhibit 1 to this report.

3. Thereafter, Ellis Malovany (the other managing director of Aquarius) and I sent a copy of the Corrective Notice to every person to whom we had previously sent either (a) a communication stating that a Zylast product was approved or endorsed by the Food and Drug Administration, or (b) a document containing the logo of the FDA.

4. We sent virtually all such Corrective Notices by email. I attach an example of such email as Exhibit 2 to this report. There were a few intended recipients of the Corrective Notice for whom we lacked a current email address, and for each such person, we either sent the Corrective Notice by fax or mail, or communicated the information orally.

Dated: May 14, 2015
New York, New York



Dan Putalik

Exhibit 1

May 1, 2015

Customer Name
Customer Company
Customer Address

Dear Customer:

We are writing to point out that, in prior communications, we stated that the Zylast products were approved or endorsed by the FDA, and we used the FDA logo in a document we prepared and sent to some customers. This statement and the use of the FDA logo are not permitted by law. To be clear, Zylast products are marketed pursuant to an FDA Tentative Final Monograph, but they are not approved or endorsed by the FDA.

Very truly yours,

CT2:725238_v1

Exhibit 2

From: Dan Putalik <putalik@aquariusgep.com>
Sent: Tuesday, May 05, 2015 3:07 PM
To: jtillis@imperialbag.com
Subject: Aquarius GEP follow up
Attachments: Innovative BioDefense - update letter (1).pdf; CDC Guidelines 2-pager.pdf; v.1.pdf

Dear Jason,

We wanted to send you the following information. Please take a look at the attachments.

I will call to follow up with you to discuss, and we look forward to working with you moving forward.

Thanks & all the best, Dan

Dan Putalik
Managing Partner
Aquarius GEP
117 East 71st. Street
New York, NY 10021

t. 917-816-0810
f. 212-288-0137
s. redseal18
e. putalik@aquariusgep.com



Innovative BioDefense Inc.

21581 Midcrest Dr., Lake Forest, CA :: (949) 855-2885 :: www.zylast.com

Released May 1, 2015. With all of our recent successes – from winning major accounts to the *Fighting Ebola Grand Challenge* – it appears we have also succeeded in scaring our largest competitor. Purell has launched a counteroffensive against Zylast, not by trying to make a better product or compete in the marketplace, but in the courts and with a deliberate smear campaign.

After the CDC, White House Science and Technology Office, and the Department of Defense experts awarded Zylast a winner of the *Fighting Ebola Grand Challenge*, and after our significant success in the marketplace this year, it became inevitable that Purell would have to respond. They filed litigation in New York, including attempting to get a Temporary Restraining Order, alleging that Zylast makes false and misleading claims. In a transparent attempt to bully a smaller company, we were allowed less than 48 hours to respond to their allegations. They must have been shocked when our response came in – 18 pages of detailed documentation and scientific proof for every single statement that we make, with more than 200 pages of corroborating peer-reviewed papers attached. Ironically, many of these statements came from Purell papers that contradicted the statements made in their litigation. We used Purell's own papers and documentation to disprove their allegations.

Following these failing strategies, Purell is now engaging in a deliberate smear campaign, sending out information to all of their salespeople attacking Zylast. We view this as a substantial opportunity for our sales, proving that we are a legitimate and dangerous competitor to the market leader, and believe it will backfire spectacularly for Purell. (Purell is attempting to claim that their alcohol sanitizers have no safety risks – ingestion, flammability, etc. and are not irritating or drying to the hands.)

As you know from having worked with us, Zylast is committed to the highest level of scientific research and backing for our products. We have conducted more important, meaningful, well-designed and controlled clinical trials and tests in the past two years than Purell has published in the previous two decades. We have seen the clinical benefit of a persistent product in hospitals and schools, and have ongoing clinical trials in several hospitals and nursing homes that will completely revolutionize the industry.

Zylast only makes the following claims as per FDA guidelines:

- fast-acting,
- persistent,
- broad spectrum,
- kills 99.99% of germs, and
- moisturizing,

Zylast makes no claims of being anti-viral, effective against certain bacteria such as MRSA, etc. We have also provided you with scientific studies. These studies are NOT claims, but well controlled studies, usually performed by outside laboratories, and peer reviewed papers that discuss the benefits and risks

of Zylast. Our control in these studies is frequently alcohol. We will not respond to every claim from Purell, because they all can be answered by the above information. Furthermore, we as an organization will not stoop to trying to confuse the public with false and misleading statements or cast aspersions on our competitors. Zylast (and its clinical results) speaks for itself.

CDC Guidelines for Hand Hygiene

"When evaluating hand hygiene products for potential use in healthcare facilities, administrators or product-selection committees must consider factors that can affect the overall efficacy of such products, including the *relative efficacy of antiseptic agents against various pathogens and acceptance of hand hygiene products by personnel.*"

"(An Antiseptic product should be) **broad-spectrum, fast-acting, and if possible, persistent.**"

– CDC Guideline for Hand Hygiene in Healthcare Settings, 2002

	Alcohol	Non-alcohol	Alcohol	Non-alcohol	Alcohol	Non-alcohol
Alcohol Sanitizers	✓	✓				
Non-alcohol Products		✓		✓		✓
	✓	✓	✓	✓	✓	✓

"Fast-Acting"

When the CDC recommended alcohol products in 2002, one of the major reasons was that alcohol was the only product on the market that could kill germs in 15 seconds. Non-alcohol products often took up to 2 minutes to have a similar effect.

Zylast is the only non-alcohol sanitizer to ever show superior immediate kill to alcohol sanitizers. Zylast has exceeded results for alcohol sanitizers in both the FDA Time-Kill Testing and European Hand Sanitizer Test.

	Avagard (61% ethanol)	Zylast (0.2% BZT)
<i>S. aureus</i>	99.1%	99.9997%
<i>S. epidermis</i>	>99.9%	99.9996%
<i>K. pneumonia</i>	>99.9%	99.9999%
<i>P. aeruginosa</i>	>99.9%	99.9999%
<i>E. coli</i>	>99.9%	99.9999%
<i>S. pneumonia</i>	>99.9%	99.9999%
<i>S. pyogenes</i>	98.0%	99.9999%
<i>S. marcescens</i>	>99.9%	99.9998%
<i>E. faecalis</i>	>99.9%	99.9996%

Zylast meets or exceeds the fast-acting efficacy of an alcohol-based sanitizer against bacteria

"Broad Spectrum"

Norovirus Kill



Zylast is more than 100 times as effective as alcohol sanitizer against the Norovirus

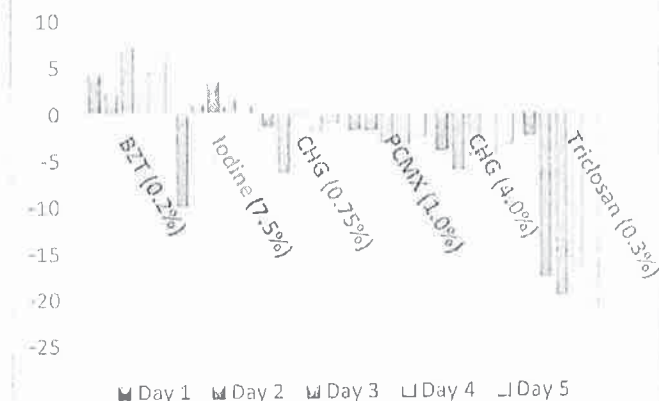
Both traditional alcohol sanitizers and Zylast are effective against a broad spectrum of bacteria, but alcohol sanitizers are relatively ineffective against many viruses. In the largest hand hygiene study ever conducted, sponsored by the CDC, medical facilities that rely on alcohol were shown to have six times the Norovirus outbreaks of facilities that did not have alcohol sanitizers. In contrast, Zylast kills 99.97% of the Norovirus on contact, more than 100 times more effective than alcohol alone.

Zylast has been tested against the 25 different, FDA-specified bacteria in Time-Kill testing, and has been shown to be effective within 15 seconds against both gram-positive and gram-negative bacteria.

"Acceptance by Personnel"

"Because HCWs <health care workers> may wash their hands....as many as 30 times per shift, the tendency of products to cause skin irritation and dryness is a substantial factor that influences acceptance, and ultimate usage"

– CDC Guideline for Hand Hygiene in Healthcare Settings, 2002

Dermal Moisture

Zylast actually puts moisture back into the skin,
preventing dryness and irritation

Studies show very low compliance (40-50%) with hand hygiene protocols, and the largest reason is skin irritation associated with current products. Alcohol sanitizers work by dehydrating the bacteria – unfortunately, they do the same to the skin. The CDC Guidelines report that at least 25% of healthcare workers have contact dermatitis from their current products, and 85% have reported painful, cracked skin during their careers.

Zylast is different, water-based and without the drying nature of alcohol sanitizers. The active ingredient, BZT, actually *increases* moisture in the skin, and there is no skin irritation even after 100 uses daily for 5 straight days.

"Persistent"

"Persistence, defined as prolonged activity, is a valuable attribute that assures antimicrobial activity during the interval between washings, and is important to a safe and effective healthcare personnel handwash"

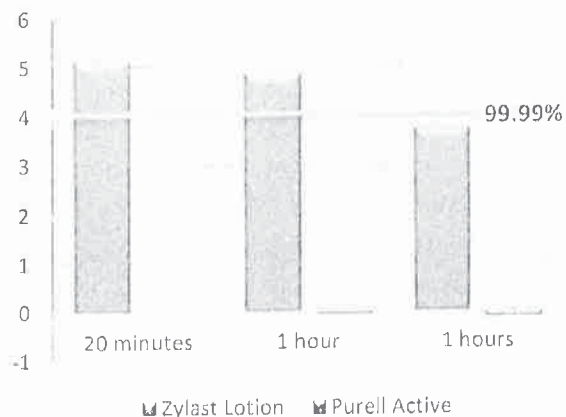
- FDA Tentative Final Monograph, Topical Antimicrobial Drug Products, 1994

"Alcohols are rapidly germicidal when applied to the skin, but they have no appreciable persistent (i.e., residual) activity."

– CDC Guideline for Hand Hygiene in Healthcare Settings, 2002

Both the FDA and the CDC emphasize the importance of a product with persistent efficacy. Alcohol sanitizers have no extended protection – as soon as they dry, the hands can become recontaminated. This means that compliance would have to be perfect in order for patients and workers to be fully protected.

In testing on human skin, Zylast was shown to kill more than 99.9% of transient bacteria (*E. coli*) at 20 minutes, 1 hour, and even 6 hours after application. Zylast has the ability to provide persistent, residual activity as emphasized by both the FDA and CDC, and best fulfills the CDC Guidelines.

Persistence on Skin

May 1, 2015

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Very truly yours,

Aquarius Global Energy Partners, LLC